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10/062,299

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Leroy E. Hood

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08/28/2006

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EXAMINER

SMITH, CAROLYN L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/062,299

Applicant(s)

HOOD ET AL.

Examiner

Carolyn L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 36-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's remarks, filed 6/9/06, are acknowledged.

Applicant's arguments, filed 6/9/06, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 22-35 are herein under examination. Claims 1-21 and 36-49 remain withdrawn as being drawn to non-elected Groups.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24-35 are rejected under 35 U.S.C. 101 because these claims are directed to non-statutory subject matter.

This rejection is maintained.

Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) a method that does not result in a physical transformation of matter MAY be statutory where it recites a concrete, tangible and useful result; i.e. a practical application.

In the instant case, the claims are directed to a method of assigning a cellular function to a component of a biochemical system via determining and comparing a multidimensional

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coordinate point and determining if the point is outside a network-associated reference expression region, and assigning a cellular function. Although a cellular function is assigned, these results are not presented in a tangible form. This assigning method does not result in a physical transformation of matter, nor is any concrete, tangible and useful result produced/recited. Therefore, these claims are not statutory.

Applicants summarize the rejection. Applicants' argue that the Board of Appeals and Interferences of the USPTO has now overturned rejections attempting to require method claims to include machine or computer processing limitations, such as a requirement for a physical transformation or an interaction with a computer. This statement is found unpersuasive. It is noted that the examiner has not "required" that the claims recite a physical transformation or interaction with a computer. The previous office action stated that where the claims do not recite a physical transformation of matter, they MAY be statutory where they recite a concrete, tangible and useful result; i.e. practical application. This is in accordance with the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) and the *In re Lundgren* decision. It is further noted that Applicant does not argue that the claims do, in fact, recite a physical transformation of matter nor does Applicant argue that the claims recite a concrete, tangible and useful result. In the instant case, neither kind of result is present, as previously set forth and reiterated above. Therefore, the claims remain rejected as being drawn to non-statutory subject matter.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Stoughton et al. (P/N 6,132,969).

This rejection is maintained and reiterated for reasons of record.

Stoughton et al. disclose laboratory and computer methods for testing and confirming how well a network model represents a biological pathway in a biological system (abstract) wherein the biological pathway in a biological system represents a biochemical system. Stoughton et al. disclose obtaining measurements for drug and pathway responses (col. 52, lines 56-62) and perturbing and monitoring components in a network model (col. 53, lines 38-64) which represents physically perturbing a component, as stated in instant claim 22. Stoughton et al. disclose the network comprises logical operators relating to input cellular constituents (components), such as mRNA and proteins, to output classes of cellular constituents which are affected by the pathway (abstract), which represents assigning a cellular function to components (col. 10, line 61 to col. 11, line 3), as stated in instant claims 22, 24, and 30. Stoughton et al. disclose use of positionally addressable transcript microarrays which are ordered and reproducible matrices for easy comparison with each other and capable of containing single sites per specific mRNA (col. 45, lines 17-39, col. 46, lines 58-67, and col. 51, lines 39-49) and

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making measurements of graded drug exposure and of graded levels of modification/perturbation control parameters (col. 52, lines 1-17) wherein the microarrays inherently involve mRNA locations containing x and y dimensions (multidimensional coordinate points) for components of a physically perturbed system including n parameters (i.e. drug exposure and levels of perturbation) corresponding to the number of measured components within the biochemical system, as stated in instant claims 22, 24, and 30. Figure 9 illustrates positioning “0” state over “1” state (col. 28, lines 3-22) which represents comparison to a reference region, as stated in instant claims 22, 24, and 30. Stoughton et al. disclose comparing relative changes in the biological system in response to perturbations of the network (abstract and col. 8, lines 40-41 and col. 8, line 64 to col. 9, line 12). Stoughton et al. disclose comparing relative changes between two states in a biological system (col. 3, lines 15-20) including normal reference “0” and perturbed expression “1” states (col. 7, lines 50-64 and col. 8, lines 34-52), which represents comparison to a reference expression region, as stated in instant claims 22, 24, 27, 30, and 33. Stoughton et al. disclose predicting how output classes behave in response to the chosen experiments by finding measures (multidimensional coordinate points) of relative change of cellular constituents (components) and finding goodnesses of fit (“the conformity between an experimental result and theoretical expectation”, according to Merriam-Webster’s online dictionary) of each observed component to an output class (reference data element region) based on strongest correlations (abstract), which represent a linkage to the perturbed biochemical network. Stoughton et al. disclose analyzing a scanned image by using an image gridding program that creates a spreadsheet of the average hybridization at each wavelength at each site (col. 51, lines 1-5). Stoughton et al. disclose the relative abundance of mRNA is scored as a

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perturbation if there is a difference of the two sources of mRNA tested (col. 51, lines 14-27) which represents determining if the multidimensional coordinate point is within or outside the reference region and a difference (outside the region) is indication of linkage to a perturbation, as stated in instant claims 22, 24, and 30. Stoughton et al. disclose assigning a cellular function to components of a network or pathway (col. 10, line 58 to col. 11, line 3), as stated in instant claims 22, 24, and 30. Stoughton et al. disclose determining the overall goodness of fit of the network model (network-associated expression region) from the individual goodnesses of fit of each observed component (abstract), which also represents determining the multidimensional coordinate point representing a data element of a set of components in a network, as stated in instant claim 24. Stoughton et al. disclose observing a system's response to known inputs via gene expression and/or protein abundances (col. 2, first paragraph), as stated in instant claims 23, 26, 28, 29, 32, 34, and 35. Stoughton et al. disclose the biological system as a cell, organism, and patient (col. 5, line 67 to col. 6, line 1) which represents the biochemical system, as stated in instant claims 25 and 31.

Thus, Stoughton et al. anticipate the limitations in claims 22-35.

Applicants' arguments filed 6/9/06 have been fully considered but they are not persuasive. Applicants state that the multidimensional coordinate point as claimed includes n parameters wherein n corresponds to the number of measured components within a biochemical or constituent system and argue that Stoughton et al. do not describe determining a multidimensional coordinate point as described and claimed in the instant application. This statement is found unpersuasive as several passages from Stoughton et al. represent such a point

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(i.e. col. 45, lines 17-39; col. 46, lines 58-67; col. 51, lines 39-49; and col. 52, lines 1-17).

Applicants state they have specifically defined “multidimensional coordinate point” and have shown how it distinguishes over Stoughton et al. in their previous responses. It is noted that Applicants’ arguments from previous responses were deemed unpersuasive. Applicants reiterate their arguments that the “multidimensional coordinate point” is a coordinate defined by “n” parameters wherein n corresponds to the number of measured components within a biochemical or constituent system and argues that the claimed point is distinct from the descriptions of Stoughton et al. This argument has already been found unpersuasive, as discussed above. Applicants summarize Stoughton et al. (col. 45, lines 17-39; col. 46, lines 58-67; col. 51, lines 39-49; col. 52, lines 1-17) and argue that these passages are silent as to determining a multidimensional coordinate point that includes n parameters wherein n corresponds to the number of measured components within a biochemical or constituent system. This statement is found unpersuasive as Stoughton et al. disclose use of positionally addressable transcript microarrays which are ordered and reproducible matrices for easy comparison with each other and capable of containing single sites per specific mRNA (col. 45, lines 17-39, col. 46, lines 58-67, and col. 51, lines 39-49) and making measurements of graded drug exposure and of graded levels of modification/perturbation control parameters (col. 52, lines 1-17) wherein the microarrays inherently involve mRNA locations containing x and y dimensions (multidimensional coordinate points) for components of a physically perturbed system including n parameters (i.e. drug exposure and levels of perturbation) corresponding to the number of measured components within the biochemical system. Stoughton et al. disclose determining the overall goodness of fit of the network model (network-associated expression region) from the

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individual goodnesses of fit of each observed component (abstract), which also represents determining the multidimensional coordinate point representing a data element of a set of components in a network. Stoughton et al. disclose observing a system's response to known inputs via gene expression and/or protein abundances (col. 2, first paragraph). Applicants argue that Stoughton et al.'s positionally addressable transcript microarrays with single sites do not refer to determination of a multidimensional coordinate point; however, such a point is recited by Stoughton et al. in its broad and reasonable interpretation. It is noted that the array interpretations of Stoughton et al. as set forth in the rejection above still encompass the instant claims due to broadly written claim language. Applicants' arguments are deemed unpersuasive for the reasons given above.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Yolanda Chadwick whose telephone number is (571) 272-0514.

August 14, 2006

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
8/21/06